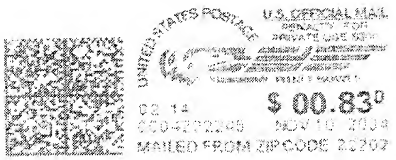
Organization TC1600 Bldg./Room REVISED

U. S. DEPARTMENT OF COMMERCE
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
IF UNDELIVERABLE RETURN IN TEN DAYS

OFFICIAL BUSINESS



AN EQUAL OPPORTUNITY EMPLOYER

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,883	10/06/2000	Bernard R. Brodeur	047998/0197	3090

23599 7590 11/10/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/684,883	BRODEUR, BERNARD R.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-129 and 131-196* is/are pending in the application.

4a) Of the above claim(s) *91-123,126,131,132 and 138-169* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124,125,127-129,133-137 and 170-196* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2004 has been entered.

Claim Rejections - 35 USC § 112

1. The rejection of claims 124, 127-130, 133-137, 170-174, 178, and 180-181 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants arguments.

2. The rejection of claims 133-137, 170-173, and 180-181 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine comprising SEQ ID NO: 2, does not reasonably provide enablement for vaccine compositions which hybridize under stringent conditions is withdrawn in view of Applicants arguments.

3. The rejection of claim 124 rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "stringent conditions" is maintained.

Applicants are asserting that the claims are not interpreted in a vacuum, and a skilled worker, upon reading the specification would understand the scope of the claims. Applicants further point towards the Written Description Guidelines as evidence that the language of stringent conditions is acceptable.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that a skilled worker, upon reading the specification would understand the scope of the claims, however without guidance as to what conditions are considered to be "stringent" one of skill in the art would simply be unable to determine the metes and bounds of the claims, since the scope of nucleic acid molecules which will hybridize to the reference sequence is directly related to the "stringent conditions" which are used. Furthermore, there is simply no scientifically agreed upon conditions which are deemed to be "stringent." Furthermore, *In re Steele* 134 USPQ 292 (CCPA 1962) has set forth that both the Examiner and Board were both wrong in relying on speculative assumptions as basis for claim interpretation.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)

Finally, Applicants point towards the Written Description Guidelines as evidence that the language of stringent conditions is acceptable. However, this guidance is directed towards meeting the written description guidelines, it is simply providing general concepts of subject matter which will meet this requirement, not absolutely

allowable claim language. Applicants should further note that the precise conditions which constituted "stringent conditions" were also set forth in the Example provided by the Written Description Guidelines.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 124, 133-137, 170, 172, 174, and 180-181 under 35 U.S.C. 102(a) as being anticipated by Merks et al is maintained. Additionally, this rejection is applied to newly submitted claims 182-196.

Applicants are asserting that Merks describe over 800 hybridoma clones, only one of which produces an antibody which recognizes a cell surface protein, and that this antibody (deposited with the ATCC) is not publicly available. Applicants assert that without this antibody there is no way to identify the surface antigen, let alone isolate it. Applicants further assert that the "20 kD" polypeptide of Merks is present in crude extract, not free of any other Neisseria meningitides polypeptides. Finally, Applicants assert that Merks do not provide the gene, so it could not be produced recombinantly.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that Merks describe over 800 hybridoma clones, only one of which produces an antibody which recognizes a cell surface protein, and that this antibody (deposited with the ATCC) is not publicly available. However, the antibody is not required to isolate the identified protein. Merks describe resolving the proteins via SDS gels starting with cell lysates. (See page 10). A band in the vicinity of "20 Kd" would be isolated, and free from other proteins, thereby addressing each and every limitation in the claims. Furthermore, this band was stained via Coomassie blue, and is clearly an antigenic surface polypeptide since the antibody deposited with the ATCC was demonstrated as binding this protein on the surface of Neisseria. (See page 10 again).

Finally, Applicants assert that the "20 kD" polypeptide of Merks is present in crude extract, not free of any other Neisseria meningitides polypeptides, and that since Merks does not provide the gene, the polypeptide could not be produced recombinantly. However, as set forth above, Merks isolated the polypeptide via SDS gels, this results in a protein band which is isolated and free from other polypeptides which would migrate faster or slower. Applicants further assert that since Merks does not provide the gene, the polypeptide could not be produced recombinantly. However, Applicants are respectfully directed to the claims, which recite a polypeptide. How the polypeptide is produced not afforded patentable weight. Accordingly, isolation of the polypeptide via SDS gels is anticipatory of the protein produced recombinantly.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

5. Claims 124-125, 127-129, 133-137, 170-196 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "an apparent molecular weight of 22 kDa." Molecular weights will vary depending upon the method and conditions employed (e.g., reducing or non-reducing conditions). Accordingly, one of skill in the art would be unable to determine the metes and bounds of the claimed invention without guidance as to the method and conditions used to determine the molecular weight of the claimed protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
November 9, 2004